K120943 #1/2

# 510(k) Summary

SEP 2 1 2012

## ArthroCare® Corporation

### SpeedLock® HIP Knotless Fixation Implant

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**General Information**

| | |
|---|---|
| Submitter Name: | ArthroCare Corporation |
| Address | 7000 West William Cannon Drive<br>Building One<br>Austin, TX 78735 |
| Contact Person: | Cheryl Frederick<br>Director, Regulatory Affairs |
| Date Prepared: | September 17, 2012 |

**Device Name**

| | |
|---|---|
| Proprietary: | SpeedLock® HIP Knotless Fixation Implant |
| Common: | Bone Anchor, Fastener, Fixation, Soft Tissue |
| Classification: | Class II |
| Product Code: | MBI |
| CFR Section: | 21 CFR 888.3040 |

**Predicate Device**

The SpeedLock HIP Knotless Fixation Implant is substantially equivalent to the Smith & Nephew Bioraptor® Knotless Suture Anchor cleared under K071586 (August 17. 2007) and the Smith & Nephew Knotless Instability Anchor cleared under K093428 (December 17, 2009) as well as to ArthroCare's SpeedLock Knotless Fixation Device cleared under K111044 (August 9, 2011).

**Description**

The SpeedLock HIP Knotless Fixation Implant (SpeedLock HIP) is a bone anchor with inserter handle designed for use in arthroscopic and orthopedic procedures. The SpeedLock HIP is a knotless fixation device: surgical knots are not necessary for the fixation of suture to tissue.

The SpeedLock HIP consists of two primary parts: a PEEK bone anchor and an anchor inserter, which is preloaded with the anchor. The anchor inserter is a disposable tool.

The entire product is packaged in a tray with a Tyvek® lid, and the finished product is sterilized by ethylene oxide. Both the anchor and inserter are designed for single use only.

The SpeedLock HIP Knotless Fixation System consists of the 3.4 mm SpeedLock HIP anchor and associated instruments for implanting the anchor into bone. In accordance with the ArthroCare Product

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Development Process, testing was performed to demonstrate the proposed device is substantially equivalent to the predicate devices. This mechanical testing was performed in accordance with the requirements of the FDA Guidance Document, *Testing Bone Anchor Devices*, April 1996; results indicated substantial equivalence for the proposed device.

**Intended Use/Indications For Use**

The SpeedLock HIP Knotless Fixation Implant is indicated for use in fixation of soft tissue to bone in the hip. Examples of such procedures include:

- Hip capsule repair
  - Acetabular labrum reattachment

**Non-Clinical Data**

Side by side bench testing was performed on both the proposed and predicate devices in accordance with the FDA Guidance Document, *Testing Bone Anchors*, April 1996. This *in vitro* testing involved insertion of the anchors in a simulated human bone substrate followed by both static and cyclic fatigue testing.

The test results demonstrate that the SpeedLock HIP Knotless Fixation Implant meets all design, performance, and safety specifications. Based on the test results, the proposed device is substantially equivalent to the predicate device

**Clinical Data**

No clinical or animal data are included in this submission.

**Summary**

All testing demonstrates that the SpeedLock HIP Knotless Fixation Implant performs as intended and has acceptable mechanical properties when used in accordance with its labeling.

As the proposed device's intended use and technological characteristics are comparable to the predicate devices, we believe that the SpeedLock HIP Knotless Fixation Implant is substantially equivalent to the Smith & Nephew Bioraptor Knotless Suture Anchor as well as to the ArthroCare SpeedLock Knotless Fixation Device. The minor differences between the SpeedLock HIP and the predicate devices do not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Arthrocare Corporation
% Ms. Cheryl Frederick
Director, Regulatory Affairs
7000 West William Cannon Drive, Building 1
Austin, Texas 78735

SEP 21 2012

Re: K120943
Trade/Device Name: SpeedLock® HIP Knotless Fixation Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: September 7, 2012
Received: September 10, 2012

Dear Ms. Frederick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

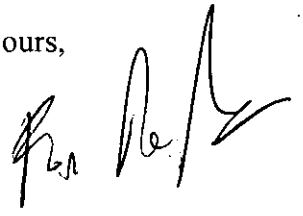
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** Not yet assigned K120943

**Device Name:** SpeedLock® HIP Knotless Fixation Implant

**Indications for Use:**

The SpeedLock HIP Knotless Fixation Implant is indicated for use in fixation of soft tissue to bone in the hip. Examples of such procedures include:

- Hip capsule repair
  - Acetabular labrum reattachment

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120943